Chapter 23 – Control of Narcotics and Other Controlled Drugs Including Alcohol (REDACTED)

23.1 Purpose

Paragraphs 23.2 through 23.14 and Appendix 23 A through D below set forth general policy and procedures relating to the procurement, handling, and disposition of narcotics and other controlled drugs except alcohol. Paragraph 23.15 below sets forth general policy and procedures relating to the procurement, handling, and disposition of tax-free alcohol.

23.2 Applicability

This manual is applicable to: (1) all Ames Employees; and (2) all persons and entities who agree in writing to comply with this manual.

23.3 Definitions

1. **Drug Control Officer:** The Drug Control Officer is the Ames Chief Medical Officer or his/her designee.
2. **Inventory Officer:** The Inventory Officer is the Ames Safety Officer. The Ames Director has appointed this person, in writing, to perform the duties outlined in Paragraph 23.11.
3. **Authorized Person:** Authorized Person means a person who is specifically authorized in writing by the Drug Control Officer to use narcotics and other controlled drugs at Ames Research Center (see Section 23.5.3 Narcotics & Other Controlled Drugs below).
4. **Authorized Narcotics Shipping & Receiving Custodian:** Authorized Narcotics Shipping and Receiving Custodian means an employee of the Logistics Branch who is authorized to receive, temporarily hold, deliver to the Drug Control Officer, and ship narcotics and other controlled drugs.
5. The Drug Control Officer will appoint, in writing, with the concurrence of the Chief, Logistics Branch, one employee and one or more alternates of the Logistic Branch to act in this capacity.
6. Copies of the memorandum of appointment will be provided to the Chief Logistic Branch, and the appointees.
7. **Authorized Narcotics Purchase Officer:** Authorized Narcotics Purchase Officer means an employee of the Acquisition Division who is authorized to place orders for narcotics and other controlled drugs.

The cognizant Branch Chief of the Acquisition Division will appoint an employee and one or more alternates, in writing, to act in this capacity. Copies of the memorandum of appointment will be provided to the Drug Control Officer and the appointees.

23.4 Drug Control Officer

1. The Ames Drug Control Officer is responsible for the control and accountability of all controlled substances and as such will be responsible for the procurement, use, and disposal of all narcotics and other controlled drugs by authorized ARC users. Note: Controlled substances are sometimes taken to shuttle landing/launch sites.

2. The Drug Control Officer will:
   - Ascertain compliance with Federal and state laws and regulations pertaining to narcotics and other controlled drugs.
   - Serve as an advisor for the Center on matters pertaining to narcotics and other controlled drugs.
   - Establish, revise, and maintain a list of controlled drugs in common use at Ames.
   - Review and approve (or disapprove) requests for authorization to use narcotics and other controlled drugs (i.e., requests to become an "Authorized Person" - see Section 23.5.3 Narcotics & Other Controlled Drugs below).
   - Maintain a file of approved applications (on ARC Forms 564 - see Section 23.5.3 Narcotics & Other Controlled Drugs below).
   - Maintain records of all narcotics and other controlled drugs received and disposed of by each Authorized Person (on ARC Forms 565 - see Section 23.7.4 Authorized Narcotics Shipping & Receiving Custodian (or alternate), 23.8 Procedures For Transfer Of Custody (Between Authorized Persons), 23.9 Delivery Procedures and 23.10-1 (white) and 2 (yellow) to the Authorized Person for his/her inventory and disposition records.)
   - Take appropriate action in the event unusual ordering or prescribing patterns or significant excess stocks are discovered.

23.5 Request For Authorization To Use Narcotics and Other Controlled Drugs

23.5.1 Registration

1. Ames Research Center is registered with the Drug Enforcement Agency (DEA) for authority to order and dispense controlled substances. This registration must be renewed every three years.
2. Registration under the business activity "Practitioner" covers the activities for clinical management of human and animal investigative subjects and for research on the pharmacological kinetics of controlled drugs. (The applicable registration form is shown in Appendix B.)

23.5.2 Schedule I Drugs

The use of Schedule I drugs (i.e., those opiates, opium derivatives, and hallucinogenic substances with no currently accepted medical use in treatment) at Ames Research Center is not authorized unless prior approval of the proposed research activity is obtained from the Director, Office of Occupational Medicine, NASA Headquarters.

All use of Schedule I drugs for research involving human subjects must be reviewed and concurred in by the Human Research Institutional Review Board (HRIRB) before requesting Headquarters approval. Protocol for research with Schedule I drugs must be filed with and be approved by the US Drug Enforcement Administration.

23.5.3 Narcotics and Other Controlled Drugs

23.5.3.1 General

Only personnel specifically authorized - called "Authorized Persons" - are permitted to work with narcotics and other controlled drugs. The approvals of the person's Division Chief and the Drug Control Officer are required for authorization. Procedures for obtaining authorization are as follows

23.5.3.2 Applicant

Complete an ARC Form 564A (Apr 96)E, Application for Authorization to Use Narcotics and other Controlled Drugs. Forward completed form (both copies) through channels to Division Chief.

1. To conduct research with controlled substances listed in Schedule I, the Authorized Person must furnish three copies of a research protocol. The protocol must contain, inter alia, the following information (see 21 CFR 1301.33):
   - Name, address, and DEA (BND) registration or copy of application for same. (Information supplied by the Medical Services Officer.)
   - Institutional or other affiliation.
   - Qualifications, including curriculum vitae and relevant bibliography of the principal investigator and co-investigators where applicable.
   - Title of project.
   - Statement of the purpose.
   - Name of the controlled substance(s) involved, reasons for using particular drug(s), and the amount of each needed (amount per experiment and total number of experiments), and the source of material.
   - Description of the research to be conducted, including experimental design, capabilities for chemical characterization of the controlled substances and where appropriate number and species of research subjects, dosage and route of administration, and contemplated duration of project. (The complete research protocol should be included in this section or attached as an appendix.)
   - Location where research will be conducted and description of the facilities.
   - Statement of the security provisions for storing and dispensing the controlled substances in order to prevent diversion. Description of method of documenting record of use including inventory form and list of individuals having access to drugs with their qualifications.
   - Description of provisions for medical care of human research subjects during and after experimentation.
2. Procedures for increasing the quantity of controlled substances or varying the research protocol
   - In the event that the Authorized Person desires to increase the quantity of a controlled substance used for an approved research project, the Person must submit a new request stating the additional quantity needed and he justification for the request.
   - In the event the Authorized Person desires to conduct research beyond the variations provided in the approved protocol (excluding any increase in the quantity of the controlled substance requested or the research project as outlined above), he or she must submit three copies of a supplemental protocol describing the new research and omitting information from the supplemental protocol that has been stated in the original protocol. Supplemental protocols must be processed and approved or denied in the same manner as original research protocols.
   - If the research involves the use of human subjects, approval must be obtained from the HRIRB. (See APG 7170-1 for procedures for conducting human research.)

23.5.3.3 Division Chief

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23.5.3.4 Drug Control Officer

REDACTED

23.6 Security and Handling

1. Narcotics and other controlled drugs and preparations containing these drugs must be properly safeguarded at all times and securely kept in a locked nonportable safe or locker (in some cases, a refrigerator), where they will be available for inspection by properly authorized officers, agents, and representatives of the Drug Enforcement Administration and the Inventory and Security Audit Team.
2. In order to fix specific responsibility for the custody and control of narcotics and other controlled drugs, keys or combinations to narcotic and controlled drug lockers or safes will be issued only to Authorized Persons, the Authorized Narcotics Shipping and Receiving Custodian and alternates, and other persons designated by the Drug Control Officer. The Protective Services Office will control key and safe combination issues, and duplicate keys or copies of combinations will be kept in sealed envelopes by the Security Officer in his safe for use in case of emergency.
3. Any product or residue resulting from the use of a drug or preparation which is to be retained for further use, research, instruction, or analysis must be placed in a container legibly labeled with the name of the product or residue and the date produced. The material must be stored in the same manner as the drug from which it came.
4. All containers used for holding and storing drugs must be properly labeled with a Narcotic and Controlled Drug Signal (ARC Form 571) giving the name of the drug, the original quantity, the strength or concentration, and the date of receipt or preparation. The date of receipt of all incoming drugs must be printed on the label in ink.

23.7 Purchase Request Procedures for Narcotics and Other Controlled Drugs

Note: Purchase requests for narcotics and other controlled drugs must be originated by Authorized Persons only, and routing and approval procedures differ in some respects from the standard purchase request procedures set forth in AMM, 5150-2 "Purchase Request."

23.7.1 Authorized Person

REDACTED

23.7.2 Approving Official(s)

REDACTED

23.7.3 Drug Control Officer

REDACTED

23.7.4 Authorized Narcotics Shipping and Receiving Custodian (or alternate)

Hold Copies 3 and 4 of approved ARC Form 565 in suspense pending receipt of drug. After receipt of drugs, sign and date Section III and make delivery to the Drug Control Officer-as set forth in Paragraph 23.9.2 below.

23.8 Procedures for Transfer of Custody (Between Authorized Persons)

1. All transfers of narcotics and other controlled drugs will be made to and through the Central Drug Repository as authorized by the Drug Control officer.

2. Gaining Authorized Person
   - Enter preparation date and information called for in Sections 1 and II of ARC Form 565. Use a separate form for each drug or form of drug.
   - Route entire ARC 565 form with short memorandum explaining the proposed transfer (from whom - to whom) to Drug Control Officer.
3. Drug Control Officer
   - Approve or disapprove transfer in Section III of ARC Form 565.
   - If approved:
   - Detach Copy 3 (yellow) and file in gaining Authorized Person's jacket.
   - Route Copies 2 through 6 to losing Authorized Person.
   - If disapproved, return all copies to originator, include explanation.
4. Losing Authorized Person - On receipt of Copies 2 through 6 of approved ARC Form 565, make delivery to the Drug Control Officer for transfer to the gaining Authorized Person as set forth in Paragraph 23.9 below.

23.9 Delivery Procedures

23.9.1 Applicability

The delivery procedures set forth below are applicable to:

1. The Authorized Narcotics Shipping and Receiving Custodian (or alternate) - in the case of shipments of drugs received from sources outside the Center (e.g., Purchases, etc.).
2. The losing Authorized Person - in the case of transfers between Authorized Persons on the Center premises.

23.9.2 Procedures

Deliver shipments of narcotics or other controlled drugs along with ARC Form 565 to the Drug Control Officer for transfer to the Authorized Person. Obtain the Drug Control Officer's signature in Section III as evidence of receipt. Do not make delivery to any other person.

Distribute remaining copies of ARC Form 565 as follows:

1. Copy 3 (goldenrod) – To the Drug Control Officer as evidence of delivery. (This copy to be filed in the Authorized Person's Jacket.)
2. Copy 4 (blue) - Retain by Authorized Narcotics Shipping and Receiving Custodian as evidence of delivery.
3. Copy 1 (white) and 2 (yellow) to the Authorized Person for his/her inventory and disposition records.

23.10 Procedures for Inventory and Disposition Record Maintenance

1. Authorized Person
   - Do not separate Copies 1 (white) and 2 (yellow) of ARC Form 565 until entire quantity of drug has been disposed of.
   - Keep a current (daily or each day used) inventory and disposition record in Section IV (Use Data) of form (i.e., make an entry for each portion of drug used).
   - On disposition of final portion of drug (either by use or transfer), so indicate as a final entry and forward Copy 1 to the Drug Control Officer, **REDACTED**. Retain Copy 2 for your records.

- If continuation sheets are needed, use Copies 1 and 2 from blank ARC Forms 565. Enter page numbers at the bottom of the original and continuation copies to identify them with each other.

2. Drug Control Officer
   - Retain Copy 1 for two years showing date of final disposition and then destroy.

23.11 Inventory and Security Audit Procedures

1. A representative from the Safety Office has been assigned to act as the Inventory Officer. As such s/he is Chairman of the Controlled Drugs Inventory Team. S/he must maintain a disinterested posture with respect to inventory results. The team includes one representative each from the Protective Services Office and the Logistics Branch. A representative of the Drug Control Officer is an ex officio member acting as a technical adviser to the team. All members must be designated in writing by the Ames Director.
2. The Controlled Drug Inventory Team will review and validate the entire current inventory of controlled drugs bi-annually, or as close thereto as is convenient. Inventories should be conducted by the full team. To be valid, an inventory must be performed by at least two official members of the team.
3. The team members, in the presence of the Authorized Person, must:
   - Inspect the Authorized Person's stock of drugs and his or her inventory records (ARC Forms 565) to determine if the inventory records accurately reflect the quantity of drugs on hand. When the inventory is taken, a line will be drawn under the last entry on the transaction form, the inventory date will be entered in the "Date" column, and the inventory quantity will be entered in the "Balance Forwarded" column. If the two balances agree, the Inventory Officer will certify the balance as correct and sign the transaction form. If the balances do not agree, they will be re-verified before action is taken in accordance with Paragraph 23.12 below. Any discrepancies traceable to arithmetical error which may occur on the inventory statement will be corrected and initialed by the Inventory Officer.
   - Ascertain that the drugs are being used and safeguarded according to the security requirements set forth in this chapter (see section 23.6 Security & Handling above).
   - Document any discrepancies in the records and any security deficiencies or improper usage.
   - Make a written record of the audit, setting forth in particular any deficiencies or misuse noted and submit the record to the Ames Director for corrective action. A copy of this record must also be placed in the Authorized Person's jacket.

23.12 Procedures in Case of Shortage or Theft

When narcotics or other controlled drugs are, or appear to be, lost or stolen, whether on the Center premises or in transit to the Center, the following steps will be taken:

1. Person responsible for the security of the drugs (Authorized Person or Authorized Narcotics Shipping and Receiving Custodian) will:
   - Immediately inform the Drug Control Officer of the circumstances by telephone or in person.
   - As soon as possible prepare and transmit to the Drug Control Officer two copies of a signed statement of the facts, including a list of the drugs lost or stolen.
2. The Drug Control Officer must promptly report the loss to the following NASA officials:
   - Ames Director.
   - Nearest Regional Inspector.
   - Ames Security Officer.

3. The Regional Inspector, or in his absence the Ames Security Officer, will report the loss to the:
   - Regional Office of the Drug Enforcement Administration (DEA) in San Francisco.
   - Director, Office of Inspections and Security, NASA Headquarters
4. The DEA report form is shown in Appendix C.
5. An investigation of any shortage must be immediately performed as directed by the Director, Office of Inspections and Security, NASA Headquarters. Investigative findings, along with actions taken as remedial measures to prevent future breaches of drug control, must he furnished to all NASA officials listed above.

23.13 Procedures for Disposal of Narcotics and Other Controlled Drugs

When it is necessary to dispose of narcotics and other controlled drugs other than by authorized use (e.g., when the material has become contaminated, has deteriorated, is no longer needed, etc.), the Authorized Person must contact the Drug Control Officer who must contact the Regional Drug Enforcement Agency Office for authority and instructions to dispose of the material. (See Appendix D for copy of DEA form to use.) The drugs must be retained until instructions are received from DEA as to the course of action to be followed in disposal.

1. The action taken in disposal and the resulting change in inventory shall be entered on Copies 5 and 6 of the Authorized Person's inventory record ARC Form 565, citing the DEA authorization.
2. The DEA instructions must be retained.
3. The Authorized Person must forward Copy 5 of ARC Form 565 to the Drug Control Officer and retain Copy 6 for his record.

23.14 Transfer of Authority

If the Drug Control Officer leaves his position or is otherwise relieved of this responsibility, the following procedures must be followed:

1. A new Drug Control Officer must be designated by the Ames Director. If possible, the DEA Regional Office should be notified at least 14 days in advance that a transfer in authority under the registration will take place.
2. An inventory must be taken by the Drugs Inventory and Security Audit Team, the outgoing Drug Control Officer, and the new Drug Control Officer, prior to the outgoing Drug Control Officer's departure. The transaction record will be annotated showing the inventory balance, the inventory date, and the signatures of all three participants verifying the inventory. Any discrepancies found during the inventory will be handled in accordance with the Procedures in Paragraph 23.12.
3. All official order forms for Schedule II drugs must be turned over to the new Drug Control Officer.

23.15 Control Of Alcohol

23.15.1 Purpose

The paragraphs below set forth the general policy and procedures relating to the procurement, handling, and disposition of tax-free alcohol for use at Ames Research Center.

23.15.2 Reference

Part 182 of Title 26, Code of Federal Regulations, "Industrial Alcohol," (IRS Publication No. 201).

23.15.3 Applicability

These provisions:

1. Apply to the withdrawal and use of all tax-free alcohol (see definition in Section 23.15.4 Definitions below).
2. Are binding on all personnel employed on the Center premises, including Ames employees, contractor employees, and research associates whose work requires the procurement and use of tax-free alcohol.

23.15.4 Definitions

1. **Custodian:** Custodian means the person responsible for reviewing the procurement, storage, and use of tax-free alcohol
2. **Tax-free alcohol:** Tax-free alcohol means ethyl alcohol of 80% or greater obtained by permit without paying federal and state taxes.

23.15.5 Custodian

1. The Acquisition Division will act as the Tax-free Alcohol Custodian.
2. Responsibilities
   - Maintain tax-free alcohol permit in current status.
   - Review procurement and supply records at least semiannually.
   - Inspect supply storage facilities at least semiannually.
   - Ensure that supply inventory records and quantity on hand tally.
   - Review usage of tax-free alcohol on a random basis. At least 25% of user branches should be reviewed annually.

23.15.6 Procurement

1. Section 5310 of the Internal Revenue Code provides that US Government agencies may withdraw alcohol tax-free from any industrial alcohol plant or bonded warehouse. Such alcohol may not be used in any food products, including beverages.
2. Part I of Form 1444, "Application by the United States or Governmental Agency for Permit to Procure Alcohol Free of Tax" must be filed and a permit issued. The application must state:
   - Name of agency; and,
   - Name of the supplying proprietor of the industrial alcohol plant or bonded warehouse and registry number thereof.

   The application must be signed by a person duly authorized by the head of the agency. The application and authorization of signature must be executed in triplicate and forwarded directly to the Director of the Alcohol and Tobacco Tax Division.
3. A reorder level and order quantity for each percent alcohol required must be established by the Custodian. The Logistics Branch must place the orders through the Procurement Division.

23.15.7 Storage and Issue

1. Tax-free alcohol must be stored in a compartment or storeroom of sufficient capacity to hold the maximum quantity of alcohol that may be possessed at any one time. It must be securely constructed of substantial materials, and all doors and windows must be equipped so that they may be securely locked.
2. Tax-free alcohol must be issued only to persons presenting a properly completed request form. This form must be approved by the user's Branch Chief. It is the responsibility of the

Branch Chief to ensure that alcohol is requested only as necessary for the research efforts of the branch and that the alcohol is properly stored and used.

3. The Logistics Branch must keep records of the alcohol on hand and the users and branches to which it has been issued. These records must be made available to the Custodian upon his request.

23.16 References

1. Controlled Substances Act, 21 U.S.C. 801 et seq.;
2. Code of Federal Regulations, Part 1300 of Title 21.
3. California Health and Safety Code, Sections 11054 and 11055.
4. Handling of Narcotics and Other Drugs Regulated Under the Controlled Substances Act of 1970, NMI 1815.1

23.17 Appendices

23.17.1 Appendix A: Definitions

23.17.1.1 Narcotic Drugs

The words "narcotic," "narcotics," or "narcotic drugs" mean any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

1. Opium, isonipecaine, coca leaves, and opiate.
2. Any compound, manufacture, salt, derivative, or preparation of opium, isonipecaine, coca leaves, or opiate.
3. Any substance (and any compound, manufacture, salt, derivative, or preparation thereof) which is chemically identical with any of the substances referred to in Subparagraphs 1 and 2 above; except that the words "narcotic," "narcotics," or "narcotic drugs" do not include de-cocainized coca leaves or extracts of coca leaves, if such extracts do not contain cocaine or ecgonine.

23.17.1.2 Depressant or Stimulant Drugs

The term "depressant or stimulant drug" means any drug that contains any quantity of:

1. Barbituric acid or any of the salts of barbituric acid.
2. Any derivative of barbituric acid which has been designated by the Commissioner of Food and Drugs (United States) under Section 502(d) of the Food, Drug and Cosmetic Act (1938) as habit-forming.
3. Amphetamine or any of its optical isomers.
4. Any salt of amphetamine or any salt of an optical isomer of amphetamine.
5. Any substance which the Commissioner, after investigation, has found to be, and by regulation designated as, habit-forming because of its stimulant effect on the central nervous system.
6. Any substance which the Commissioner, after investigation, has found to have, and by regulation designates as having, potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

23.17.1.3 Dangerous and Hypnotic Drugs

"Dangerous drug" means any drug unsafe for self-medication, except preparations of drugs defined in subparagraphs 5, 6, 8, and 9 below, designed for the purpose of feeding or treating of animals (other than man) or poultry, and so labeled, and includes the following:

1. Any hypnotic drug - "Hypnotic drug" includes acetyluria derivatives, barbituric acid derivatives, chloral, paraldehyde, sulfomethane derivatives, or any compounds or mixtures or preparations that may be used for producing hypnotic effects.
2. Aminopyrine, or compounds or mixtures thereof.
3. Amphetamine, desoxyephedrine, or compounds or mixtures thereof, except preparations for use in the nose and unfit for internal use.
4. Cinchophen, neocincphophen, or compounds or mixtures thereof.
5. Diethyl-stilbestrol, or compounds or mixtures thereof.
6. Ergot, cotton root, or their contained or derived active compounds or mixtures thereof.
7. Oils of croton, rue, savin, or tansy, or their contained or derived compounds or mixtures thereof.
8. Sulfanilamide or substituted sulfanilamides, or compounds or mixtures thereof; except preparations for topical application only, containing not more than five percent (5%) strength.
9. Thyroid and its contained or derived active compounds or mixtures thereof.
10. Phenylhydantoin derivatives.
11. Any drug which bears the legend: "Caution: Federal law prohibits dispensing without prescription."
12. Hypnotic drugs when combined and compounded with non-hypnotic drugs.

23.17.1.4 Schedules of Controlled Substances

23.17.1.4.1 Schedule I

1. The drug or other substance has a high potential for abuse.
2. The drug or other substance has no currently accepted medical use in treatment in the United States
3. There is a lack of accepted safety for the use of the drug or other substance under medical supervision.

23.17.1.4.2 Schedule II

1. The drug or other substance has a high potential for abuse.
2. The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions
3. Abuse of the drug or other substances may lead to severe psychological or physical dependence.

23.17.1.4.3 Schedule III

1. The drug or other substance has a potential for abuse less than the drugs or other substances in Schedules I and II.
2. The drug or other substance has a currently accepted medical use in treatment in the United States.
3. Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

23.17.1.4.4 Schedule IV

1. The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule III.
2. The drug or other substance has a currently accepted medical use in treatment in the United States.
3. Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

23.17.1.4.5 Schedule V

1. The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule IV.
2. The drug or other substance has a currently accepted medical use in treatment in the United States.
3. Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.

23.17.2 Appendix B: DEA Registration Form

Call the Medical Services Officer at REDACTED for a hard copy.

23.17.3 Appendix C: DEA Form 106- Drug Loss Report

Call the Medical Services Officer at REDACTED for a hard copy.

23.17.4 Appendix D: DEA Drug Form 222- Disposal Report

Call the Medical Services Officer at REDACTED for a hard copy.

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